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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/667,144

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Michael T. Carley

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WORKMAN NYDEGGER/Abbott
1000 EAGLE GATE TOWER,
60 EAST SOUTH TEMPLE
SALT LAKE CITY, UT 84111

EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/667,144	Applicant(s) CARLEY ET AL.	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,36-44,50 and 52-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,36-44,50 and 52-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10-28-10, 11-2-10, 11-5-10, 11-11-10, 11-29-10, 12-7-10, 12-13-10, 12-23-10, 1-4-11, 1-11-11, 1-18-11, 1-24-11, 1-26-11, 2-3-11, 2-23-11, 3-2-11, 3-8-11, 3-15-11, 3-17-11, 3-25-11, 3-28-11, 4-5-11, 4-13-11, 4-29-11, 5-9-11, 5-18-11.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 October 2010 has been entered.

Response to Arguments

Applicant's arguments with respect the rejections to the claims under Zadno-Azizi'893 in view of Chuter'691 or Dwyer'167 have been considered but are moot in view of the new ground(s) of rejection.

Examiner is relying on Derowe et al. (WO 99/62408, referred to as Derowe'408) in the present rejection. The Derowe'408 reference was used to reject claims in the rejection mailed 24 March 2009 (see page 2 of the Office Action). In an effort to advance prosecution, Examiner will address Applicant's arguments submitted on 24 August 2009, which were filed in response to the 3/24/09 Office Action. Applicant argues that Derowe'408 does not teach the limitation: "...the body compris[es] a plurality of looped elements defining an outer periphery of the body, each looped element including a curved outer region connected to a curved inner region, the curved outer region being out of phase with adjacent curved inner regions, adjacently

positioned looped elements being connected to form an endless sinusoidal pattern."

This limitation is no longer being claimed and therefore is considered moot.

Information Disclosure Statement

Applicant's Information Disclosure Statement, filed on 710-28-10, 11-2-10, 11-5-10, 11-11-10, 11-29-10, 12-7-10, 12-13-10, 12-23-10, 1-11-11, 1-18-11, 1-24-11, 1-26-11, 2-3-11, 2-23-11, 3-2-11, 3-8-11, 3-15-11, 3-17-11, 3-25-11, 3-28-11, 4-5-11, 4-13-11, 4-29-11, 5-9-11, 5-18-11 have been received, and entered into the record.

However, it is impractical for the examiner to review the references thoroughly with the number of references cited in this case. By initializing each of the cited references on the accompanying 1449 forms, the examiner is merely acknowledging the submission of the cited references and merely indicating that only a cursory review has been made of the cited references.

MPEP § 2004.13 states: It is desirable to avoid the submission of long lists of documents if it can be avoided. Eliminate clearly irrelevant and marginally pertinent cumulative information. If a long list is submitted, highlight those documents which have been specifically brought to applicant's attention and/or are known to be of most significance. See *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc.*, 359 F. Supp. 948, 175 USPQ 260 (S.D. Fla. 1972), *aff'd*, 479 F.2d 1338, 178 USPQ 577 (Sth Cir. 1973), *cert. denied*, 414 U.S. 874 (1974). But cf. *Molins PLC v. Textron Inc.*, 48 F.3d 1172, 33 USPQ2d 1823 (Fed. Cir. 1995).

Further, it should be noted that an applicant's duty of disclosure of material and information is not satisfied by presenting a patent examiner with "a mountain of largely irrelevant material from which he is presumed to have been able, with his experience and with adequate time, to have found the critical [material]. It ignores the real world conditions under which examiners work." *Rohm & Haas Co. v. Crystal Chemical co.*, 722 F.2d 1556, 1573 [220 USPQ 289] (Fed. Cir. 1983), cert. Denied, 469 U.S. 851 (1984). Patent applicant has a duty not just to disclose pertinent prior art references but to make a disclosure in such a way as not to "bury" it within other disclosures of less relevant prior art; see *Golden Valley Microwave Foods Inc. v. Weaver Popcorn Co. Inc.*, 24 USPQ2d 180i (N.D. Ind. 1992); *Molins PLC v. Textron Inc.*, 26 USPQ2d 1889, at 1899 (D.Del 1992); *Penn Yan Boats, Inc. v. Sea Lark Boats, Inc. et al.*, 175 USPQ 260, at 272 (S.D. Fl. 1972).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17, 37-44, 58 and 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 presents "an annular-shaped body" on line 3, however, on line 12, the claim refers to a "the generally annular-shaped body". Clarification is required.

Claim 58 and 59 recites the limitation "the spring element" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17, 37, 39- 44, 50, 52 and 54- 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Derowe et al. (WO 99/62408).

Claim 17, 40, 43, 44, 50, 55, 58, 59: Derowe'408 discloses a device (380; figure 9a) for engaging tissue at a puncture site that includes an annular shaped body (384, 386) defining a plane and disposed about a central axis extending normal to the plane. The body contains a plurality of looped elements (386) extending about a periphery of the body (see Figure 9a) that form an endless sinusoidal pattern. The device further contains a plurality of tines (382) having free distal ends that extend from the looped elements and towards the central axis of the annularly shaped body.

Derowe'408 does not disclose the specific material used to construct the embodiment of Figure 9a. However, Derowe'408 specifically teaches other embodiments of the same device constructed out of memory materials that automatically change shape into a deployed configuration (page 9, lines 19-28). Further, Derowe'408 discloses that the embodiment of Figure 9a changes into a predeployment shape in which the tines extend in the direction of the central axis (page 19, lines 24-31). In light of this, it would be obvious that the body and tines are constructed of a

resilient material so the body and tines normally lie in a planar, deployed configuration. The material is sufficiently resilient so the body and tines can be moved from the planar, deployed configuration into a transverse, pre-deployment configuration in which the tines and the free, distal ends of the tines are spread open and extend in the direction of the central axis. The body and tines will return towards the deployed configuration after the force is removed (page 19, lines 24-31). In light of Derowe'408's teachings regarding the other embodiments, it would be obvious to one of ordinary skill in the art to construct the device of Figure 9a out of a resilient material that moves between a planar, deployed configuration and a transverse, pre-deployment configuration for the purpose of automatically moving the device into the deployed configuration.

Claim 37, 39, 52, 54: Derowe'408 teaches that the straight tines comprise primary and secondary tines (382, 382).

Claim 41, 56: The device (380) of Derowe'408 is a single piece of material (Figure 9a).

Claim 42, 57: Derowe'408 does not disclose a particular material for the embodiment of Figure 9a, however, Derowe'408 discloses the use of a superelastic alloy in the embodiment described in the rejection to claim 50 (page 9, lines 19-28).

Claims 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Derowe'408 in view of Sniffen et al. (US Patent 7,169,158).

Claim 36: Derowe'408 teaches the limitations of claim 36 except for the use of arcuate tines (see the rejection to claim 17 above).

Sniffen'158 teaches a closure element for use in anastomosis that contains a plurality of arcuate tines (260, Figure 26b) around an annular shaped body for the to provide the advantage of providing more consistent and reliable connections between two vessels being connected (column 20, lines 50-63).

The function of the anastomosis closure element taught by Sniffen'158 is to create a connection between two vessels that allows blood/body fluid to flow through the connection. A further function of the anastomosis closure element taught by Sniffen'158 is to prevent blood/body fluid from leaking out of the connection created with the closure element as body fluid flows between the two vessels. Therefore, one skilled in the art of puncture closure would be motivated to look to the field of anastomosis connectors for teachings on how to minimize leakage and create a strong closure between the two vessels.

In light of this, it would be obvious to one of ordinary skill in the art to modify the device of Derowe'408 with arcuate tines, as taught by Sniffen'158, in order to provide the stated advantages.

Claims 38 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Derowe'408, as applied to claim 17 and 52, further in view of Spence et al. (US Patent 6,488,692).

Derowe'408 teaches the limitations of Claim 38 and 53 except that the primary and secondary tines have different lengths.

Spence'692 teaches a closure element (Figures 9a-9f) for use in anastomosis that contains a plurality of tines (Figures 9a-9f) around an annular shaped body for the

to provide the advantage of providing consistent and reliable connections between two vessels being connected.

The function of the anastomosis closure element taught by Spence'692 is to create a connection between two vessels that allows blood/body fluid to flow through the connection. A further function of the anastomosis closure element taught by Spence'692 is to prevent blood/body fluid from leaking out of the connection created with the closure element as body fluid flows between the two vessels. Therefore, one skilled in the art of puncture closure would be motivated to look to the field of anastomosis connectors for teachings on how to minimize leakage and create a strong closure between the two vessels.

In light of this, it would be obvious to one of ordinary skill in the art to modify the device of Derowe'408 with different length tines, as taught by Spence'692, in order to provide the stated advantages.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 4:30 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on 571-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. B./
Examiner, Art Unit 3734

/Gary Jackson/
Supervisory Patent Examiner, Art Unit 3734